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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,876	02/14/2002	Jean Fernand Armand Lacrampe	JAB 1694	9445

27777 7590 05/07/2003
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EXAMINER

BALASUBRAMANIAN, VENKATARAMAN

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 05/07/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/075,876	LACRAMPE ET AL.	
	Examiner	Art Unit	
	Venkataraman Balasubramanian	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 14-18 and 21 is/are pending in the application.
- 4a) Of the above claim(s) 16-18 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 14 and 15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>1</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' preliminary amendment, which included cancellation of claims 12, 13, 19, 20 and amendment to claims 3-8, 11, filed on 2/14/2002, is made of record. Claims 1-11, 14-18 and 21 are now pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11,14-15, drawn to compound of formula I, process of making, composition, method of use, classified in class 544, subclass 182, class 514, and subclass 242.
- II. Claim 16, drawn to process of marking a receptor, classified in classes various, subclasses various depending upon preferred embodiment of the radiolabeled compound of claim 1.
- III. Claim 17, drawn to process of imaging an organ, classified in classes various, subclasses various depending upon the preferred embodiment of the imaging agent derived from compound of claim 1.
- IV. Claim 18, drawn to intermediate compound of formula XXIII and its use, classified in class 544, subclass 383.

Claim 21 which is dependent on cancelled claim 20, is not included in the above restriction requirement.

The inventions are distinct, each from the other because of the following reasons:

Invention I and IV are independent and distinct from each other because they are directed to structurally dissimilar compounds that lack common core namely 1,2,4-

Art Unit: 1624

triazine versus piperazine. Consequently, the groups have different classifications and require separate prior art searches. They can be made and used independently. Art, which may render obvious or anticipate one of the groups would not necessarily do the same for the other group. Each can support a patent, as the compounds of each group are capable of being utilized alone not in combination with other members listed in the Markush group. Inventions I and IV are also related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful as for making other products as evidenced by the references cited in the Information Disclosure Statement (paper # 1) and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Inventions I and II-III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

Art Unit: 1624

different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product disclosed in the references cited in the Information Disclosure Statement. Similarly, the product as claimed can be used in a materially different process of using that product as evidenced by the multiple uses claimed for the instant compounds and compounds known in the prior art.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Alana Kriegsman on 5/2/2003 a provisional election was made with traverse to prosecute the invention of I, claims 1-11 and 14-15. Affirmation of this election must be made by applicant in replying to this Office action. Claim 16-18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. In addition applicants should note that claim 21 which is dependent on claim 21 is also withdrawn from consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 and 14-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

Art Unit: 1624

which applicant regards as the invention. Following reasons apply. Any claim not specifically rejected is rejected as being dependent on a rejected claim.

1. In claim 1, recitation of the phrase "N-oxides, the pharmaceutically acceptable salts and the stereochemically isomeric forms thereof" renders this claim indefinite as it is not clear whether the claim is compound claim or composition claim. Note Markush choices are not in alternate form and choices are also in plural. Replacement of the said phrase "with "N-oxide, pharmaceutically acceptable salt or stereochemically isomeric form thereof" would obviate this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 and 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Freyne et al EP 0987265.

Freyne et al. teaches several 1,2,4-triazinone compounds, which include those claimed in the instant claims for the same use as interleukin-5-inhibitors for treating eosinophil-mediated diseases such as asthma. See entire document/ Particularly, see formula I on page 2 and note especially the definition of X and R² which includes groups claimed herein for instant X and R². See table 2 and 3 on pages 25-29 for compounds.

Art Unit: 1624

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11 and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freyne et al., EP 0987265.

Art Unit: 1624

Teachings of Freyne et al., as discussed in the above 102 rejection is incorporated herein. As noted above, Freyne et al. teaches several 1,2,4-triazinyl compounds, which include those, claimed in the instant claims for the same use.

Instant claims permits in X and R² various groups, while Freyne et al. teaches only limited number of such groups as seen in the Table 2 and 3.

However, Freyne et al. teaches equivalency of those compounds exemplified in the Table 2 and 3 with those claimed for the compound of formula I in the definition of the variables groups on page 2.

Thus it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds variously substituted in 1,2,4-triazine ring and the aryl ring as permitted by the reference and expect resulting compounds (instant compounds) to possess the uses taught by the art in view of the equivalency teaching outline above.

Applicants should note that the above two rejections (102/103) are based on the fact that a) the publication date of the reference is more than one year earlier than the instant CIP of PCT application and b) that the reference is an intervening reference c) there is no priority document in the application to verify the conditions of priority are met with or not.

References cited in the Information Disclosure Statement (paper #1) are made of record.

Conclusion

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (703) 305-1674. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is Mukund Shah whose telephone number is (703) 308-4716.

The fax phone number for the organization where this application or proceeding is assigned (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

V. Balasubramanian
Venkataraman Balasubramanian

5/2/2003
